DOM05– Practices for Instrument Calibration and Maintenance

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1. Background

1.1. These practices establish calibration and maintenance requirements to ensure the accuracy and reliability of instrumental results. These practices also satisfy the requirements of the Department of Forensic Sciences (DFS) Forensic Science Laboratory (FSL) *Quality Assurance Manual*, the accreditation program standards for ISO/IEC 17025:2005, and supplemental standards.

2. Definitions

2.1. For purposes of this document, the following terms shall have the designated meanings:

DFS: Department of Forensic Sciences

DOM: Departmental Operations Manual

FSL: Forensic Science Laboratory

SOP: Standard Operating Procedures

SI: International Standard Units

QAM: Quality Assurance Manual

3. Scope

3.1. These practices apply to casework units of the FSL with instrumentation and equipment that have an effect on the validity of forensic examinations.

4. Responsibilities

4.1. The Laboratory Manager, Quality Assurance Liaison, or designee will:

4.1.1. Ensure that a list of instruments and equipment requiring calibration and/or maintenance is maintained.

4.1.2. Ensure that procedures for calibrations and maintenance are maintained.

4.1.3. Ensure that instruments and equipment are calibrated and/or maintenance is performed within the required intervals.

4.1.4. Ensure that calibration and maintenance records are complete, current, and retained.

5. Practices

5.1. Calibration

5.1.1. The **Laboratory Manager, Quality Assurance Liaison**, or **designee** will ensure that each unit maintains a record of instruments and equipment that require calibration. This record will include, at a minimum: the identity of the item of equipment and its software; the manufacturer's name, type identification, and serial number or other unique identification; checks that equipment complies with the specification; current location, where appropriate; the manufacturer's instructions, if available, or reference to their location; dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; the maintenance plan, where appropriate, and maintenance carried out to date; any damage, malfunction, modification or repair to the equipment. In addition to these records, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.1.2. Instruments or equipment that require calibration will not be used for casework if satisfactory calibration cannot be achieved or the calibration due date has passed. These instruments shall be removed from service and documented in the Equipment Binder and Quality Binder the date of removal from service, signature of removing member and reason why instrument was removed.

5.1.3. Calibration procedures or performance checks must also be satisfactorily completed on any instrument that goes outside the control of the FSL Laboratory prior to its return to service.

5.2. Calibration Procedures

5.2.1. Instruments and/or equipment requiring calibration will have documented procedures for performing calibrations. Calibration procedures may be included in the standard operating procedure (SOP) in which the instrument/equipment is used or may be written as a stand-alone SOP for calibration. These procedures will reflect current calibration requirements based on the use of the instrument/equipment and will be readily available to appropriate unit personnel. All calibrations will be performed in accordance with the appropriate calibration procedures. If these procedures are performed by external sources, casework units will verify that the calibration was completed. The Quality Assurance Liaison shall document calibration in the Quality Binder.

5.3. Reference Standards, Certified Reference Materials and Reference Materials

5.3.1. Where practicable, reference standard traceable to SI units (International System of Units) or certified reference materials will be used for calibration. In those cases where reference standards or certified reference materials are not available, an FSL-prepared standard or other reference material may be used. The unit will ensure that the properties and characteristics of the reference material are suitable for its intended purpose. All reference standards, certified reference materials or reference materials used for calibration will be uniquely identified. A certificate of traceability, if applicable, will be retained to ensure traceability.

5.4. Calibration Interval

5.4.1. The calibration interval will be documented for each instrument requiring calibration. Manufacturers' operating guidelines should be consulted to determine the correct calibration interval. However, instruments used infrequently, such that recommendations by the manufacturer cannot be followed, will be calibrated or have their calibration verified prior to use. New instruments and equipment, or instruments and equipment that have undergone repair or maintenance that affect calibration, will be calibrated or have their calibration verified before being used in casework. The Laboratory Manager, Quality Assurance Liaison, or designee will ensure appropriate actions are taken to comply with calibration intervals.

5.5. Maintenance

5.5.1. Instruments and equipment will be properly maintained. The Laboratory Manager or designee will ensure that a record of the unit's instruments and equipment that require maintenance is maintained. This record will include, at a minimum: the identity of the item of equipment and its software; the manufacturer's name, type identification, and serial number or other unique identification; checks that equipment complies with the specification; current location, where appropriate; the manufacturer's instructions, if available, or reference to their location; dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; the maintenance plan, where appropriate, and maintenance carried out to date; any damage, malfunction, modification or repair to the equipment. Instruments and/or equipment having a direct effect on the quality of the examination or evidence process will have documented procedures for the maintenance activities. Maintenance procedures may be a stand-alone maintenance document, may be incorporated into the appropriate technical SOP, or may be manufacturer-supplied procedures for maintenance. These procedures will reflect current maintenance requirements and will be readily available to appropriate unit personnel.

5.5.2. Where applicable, and in order to ensure proper functioning and prevent contamination, the laboratory shall handle, store, transport, use, and conduct planned maintenance of all measuring equipment according to the manufacturer's recommendations and instructions.

5.6. Preventive Maintenance

5.6.1. Preventive maintenance will be performed according to a regular, predetermined schedule, based on manufacturer's recommendations (as available and relevant), historical observations of problems, operating experience, and how often the instrument or equipment is used. Preventive maintenance will be documented in the maintenance records.

5.7. Corrective Maintenance

5.7.1. When an instrument cannot be properly calibrated, fails to meet the performance characteristics established for the procedures, or produces

suspect results, the instrument will be taken out of service and labeled to prevent inadvertent use until corrective maintenance is performed. Only when it is shown by calibration or a performance check to operate correctly can the instrument be returned to service. Any corrective maintenance will be documented in the maintenance records.

5.8. Performance Checks

5.8.1. In instances where calibration is not required or appropriate, performance checks should be carried out at appropriate intervals to verify that the equipment or instrument is functioning as expected. Performance check procedures may be included in the standard operating procedure (SOP) in which the instrument/equipment is used or may be written as a stand-alone SOP for performance checks. These procedures will reflect current performance requirements based on the use of the instrument/equipment and will be readily available to appropriate unit personnel. If an instrument can be affected by a power interruption, unit personnel will check the performance after a shut-down, whether deliberate or otherwise.

5.9. Malfunctioning Equipment

5.9.1. Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits shall be taken out of service. It will be isolated to prevent its use or clearly labeled as being out of service. The equipment will remain in this state until necessary repairs have been made and shown by calibration or test to perform correctly. Units will determine the effect of the malfunction, if any, on test results and implement "Control of Nonconforming Testing" in the *FSL QAM – Section 4.9*, when necessary. Any equipment that is required to be sent off site for repairs will be properly packaged according to the requests of the vendor conducting the repairs or according to the manufacturer's instructions.

5.10. Equipment Security

5.10.1. Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results. Such safeguarding will be conducted by placing passwords, where applicable, on equipment/software and security of the laboratory areas. Also, only authorized and appropriately trained individuals will be permitted to handle or use laboratory equipment or software.

6. Documentation

6.1. The following records will be generated and permanently retained:

6.1.1. Listing of instruments requiring calibration and/or maintenance.

6.1.2. Calibration and Maintenance records.

6.1.3. Certificates of traceability for reference standards.

7. References

7.1. ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland (current revision).

7.2. ASCLD/LAB-International® Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC (current revision).

7.3. Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

7.4. Forensic Science Laboratory Quality Assurance Manual (current revision)

7.5. Unit-specific *Quality Assurance Manual* (current revision)